

Don Murry
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Re: 097-12128
Permit Amendment to
CP 097-3341-00072

Dear Don Murry:

Eli Lilly and Company was issued a permit on July 27, 1994 for research and development facilities. A letter requesting an amendment to the site specific RACT plan was received on March 30, 2000. Pursuant to IC13-15-7-1, this permit is hereby amended as follows:

The page 1 of the Construction Permit CP 097-3341-00072 contains following description of the permitted equipment, which is amended by this letter:

Eli Lilly and Company

.....

is hereby authorized to construct

two pilot plant modules E and F, and portable equipment associated with the pilot plant. Furthermore, pursuant to 326 IAC 8-1-5, this construction permit will authorize Eli Lilly and Company to comply with 326 IAC 8-5-3 through alternative control requirements on the new and existing equipment in the pilot plant in Building 110.

Further, page 1 through 8 of the permit contains a list of equipment at this source.

The existing operation conditions that require amendment are as follows:

4. That pursuant to 326 IAC 8-1-5 and 326 IAC 8-5-3 the following shall be met:
 - a) volatile organic compound (VOC) emissions from pilot plant in Building 110 shall be limited to 19.01 tons/year based on a twelve month average rolled on a monthly basis.
 - b) volatile organic compound (VOC) emissions from each facility covered under 326 IAC 8-1-5 shall be limited to 15 pounds per day/33 pounds per day based on calendar month average.

For purposes of determining compliance with the daily emission limit for each facility, Lilly may calculate emissions using the following methods:

1. Using monthly mass balance data for each module to prorate a portion of the total emissions from the module to each facility.
2. Calculating emissions from solvent and waste solvent storage tanks using equations in section 4.3 of AP-42.
3. When a portable emitting facility operates independently of any stationary emitting facility and vents emissions separately from any stationary emitting facility, then the emissions from that portable facility shall be attributed to that portable facility. When a portable emitting facility is connected to and operates in conjunction with any stationary emitting facility and the emissions from portable facility are vented with the emissions from the stationary facility, the emissions from the portable facility shall be attributed to the stationary facility.

c) the primary reactor condensers will operate during reactor venting, material transfer, distillation, and storage of filtrates in reactors, which are transferred from the filters. The primary reactor condensers working fluid inlet temperature will be - 10 degrees C or colder for mixtures that will not freeze at - 10 degrees C (includes most non-aqueous streams).

d) the working fluid temperature at the inlet and outlet of the condensers shall be recorded while condensers are in operation.

e) any startup, shutdown, or malfunction period causing excessive emissions shall be recorded. The records shall include the start time, end time, and the estimated quantity of excess emissions emitted during the occurrence.

5. That a log of information necessary to document compliance with condition no.4, shall be maintained. These records shall be kept for at least the past 24 month period and made available upon request to the Office of Air Management. A quarterly summary shall be submitted to:

Environmental Resources Management Division
Air Pollution Control Section
Enforcement Branch, Enforcement Manager
2700 South Belmont Avenue
Indianapolis, Indiana 46221

within 60 days after the end of the quarter. The volatile organic compounds (VOC) emissions shall be reported in the format attached.

The page 1 of the Construction Permit CP 097-3341-00072, description of the permitted equipment is modified as follows:

Eli Lilly and Company

.....

is hereby authorized to construct

two pilot plant modules E and F, and portable equipment associated with the pilot plant for "Research and Development activities". Furthermore, pursuant to 326 IAC 8-1-5, this construction permit will authorize Eli Lilly and Company to comply with 326 IAC 8-5-3 through alternative control requirements on the new and existing equipment in the pilot plant in Building 110.

The equipment list on page 1 through 8 of the permit is deleted and replaced by following description:

“Research and Development activities” are activities conducted under close supervision or technically trained personnel that are not engaged in the manufacture of products for sale, exchange for commercial profit, or distribution, except in a de minimis manner and the primary purpose of which is to:

- (i) test more efficient production process;
- (ii) test methods for preventing or reducing adverse environmental impacts; or
- (iii) conduct research and development into new processes and products.

Support activities necessary to the research and development activities are considered to be part of the research and development activities. Support activities do not include the provision of power to research and development activities from sources that provide power to multiple projects or from sources that would otherwise require permitting, such as boilers that provide power to a source or solid waste disposal units, such as incinerator.

The amended operation conditions are as follows:

4. That pursuant to 326 IAC 8-1-5 and 326 IAC 8-5-3 the following shall be met:
 - a) the volatile organic compound (VOC) emissions from pilot plant in Building 110 shall be limited to less than 10 tons per 12 consecutive months period rolled on monthly basis;
 - b) the primary reactor condensers shall operate during reactor venting, material transfer, distillation, and storage of filtrates in reactors, which are transferred from the filters. The primary reactor condensers working fluid inlet temperature shall be - 10 degrees C or colder for mixtures that will not freeze at - 10 degrees C (includes most non-aqueous streams); and
 - c) the applicant shall submit a quarterly certification that the condensers were operating at all times as required by the condition 4.b. If exceptions to this occur, note the exception, indicate what caused the exception, and how it was corrected.
 - d) the emission units, which have potential to emit VOC greater than 15 pounds per day shall comply with requirements of 326 IAC 8-5-3 (b)(3) through (6) in addition to the site-specific RACT plan requirements.
5. A log of information necessary to document compliance with condition no.4, shall be maintained. These records shall be kept for at least the past 36 month period and made available upon request to the Office of Air Quality. The certification that the condensers were operating at all times shall be submitted quarterly to the following address:

Environmental Resources Management Division
Air Pollution Control Section
2700 South Belmont Avenue
Indianapolis, Indiana 46221

within 60 days after the end of the quarter. Additionally, an annual summary of volatile organic compounds (VOC) emissions shall also be submitted to above address. The VOC emissions shall be reported within 60 days after the end of the calendar year in the format attached.

The Quarterly Solvent Usage Report on page 12 of 13 of the original permit is replaced with a new form that is attached to this letter. The old reporting form is shown on page 5 of 6 of this letter and new form is shown on page 6 of 6 of this letter. The Quarterly Solvent Usage Report on page 13 of 13 of the permit is deleted because this limit is removed from the permit.

All other conditions of the permit shall remain unchanged and in effect. Please attach a copy of this amendment to the front of the original permit.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter, please contact Gurinder Saini, at (800) 451-6027, press 0 and ask for Gurinder Saini or extension 3-0203, or dial (317) 233-0203.

Sincerely,

Paul Dubenetzky, Chief
Permits Branch
Office of Air Quality

GS

cc: File - Marion County
U.S. EPA, Region V
Marion County Health Department
Environmental Resources Management Division - Indianapolis
Air Compliance Section Inspector – Dick Sekula
Compliance Data Section - Karen Nowak
Administrative and Development - Janet Mobley
Technical Support and Modeling - Michele Boner

Eli Lilly and Company
Indianapolis

CP 097-3341
Plt ID 097-00072
Review Engineer: T.P.Sinha

Indianapolis Air Pollution Control Section
Quarterly Solvent Usage Report

Eli Lilly and Company
Indianapolis, Indiana
Pollutant: VOC

Facility I.D.: Pilot Plant
Construction Permit No.: 097-3341
Plt ID No.: 097-00072
Limit (tons per 12 month period) :19.01 tons

Monthly Emissions Data

Year: _____

<u>Month</u>	<u>No. of Batches Processed</u>	<u>Tons of VOC Emitted this Month*</u>	<u>Tons of VOC Emitted in Last 12 Months</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

* Production records which complies with this emission limits should be recorded and submitted with report.

Submitted By: _____

Date Submitted: _____

Indianapolis Air Pollution Control Section
Annual VOC Emissions Report

Eli Lilly and Company
Indianapolis, Indiana
Pollutant: VOC

Facility I.D.: B110 Pilot Plant
Construction Permit No.: CP 097-3341
Plt ID No.: 097-00072
Limit (tons per 12 month period rolled on monthly basis): 10 tons

Monthly Emission Data

Year: _____

<u>Month</u>	<u>Tons VOC emitted this Month*</u>	<u>Tons VOC Emitted in Last 12 Months</u>
<u>December (previous year)</u>	_____	_____
<u>January</u>	_____	_____
<u>February</u>	_____	_____
<u>March</u>	_____	_____
<u>April</u>	_____	_____
<u>May</u>	_____	_____
<u>June</u>	_____	_____
<u>July</u>	_____	_____
<u>August</u>	_____	_____
<u>September</u>	_____	_____
<u>October</u>	_____	_____
<u>November</u>	_____	_____

* Production records that show compliance with this emission limit will be maintained on site and will be made available upon request.

Submitted By: _____
Date Submitted: _____

**Indiana Department of Environmental Management
Office of Air Quality**

Indianapolis Environmental Resource Management Division

**Technical Support Document (TSD) for an Amendment to a Construction
Permit**

Source Background and Description

Source Name:	Eli Lilly & Company – Lilly Technology Center
Source Location:	1555 South Harding Street, Indianapolis IN 46221
County:	Marion
SIC Code:	2834
Permit No.:	097-3341-00072
Operation Permit Issuance Date:	July 27, 1994
Amendment No.:	097-12128-00072
Permit Reviewer:	Gurinder Saini

The Office of Air Quality (OAQ) has reviewed an amendment application from Eli Lilly & Company – Lilly Technology Center relating to the operation of research and development facilities.

Explanation of Modification

The Permittee has requested to make the following changes to their Construction Permit:

1. Replace the equipment list on page 1 through 8 of the Permit with the general description of the “Research and Development activities” under the Part 70 operating permit rule.
2. Modify the limit for the Volatile Organic Compounds (VOC) emissions from this Source to 10 tons per year from 19 tons per year.
3. Remove 15 lb/day and 33 lb/day VOC emission limit and the associated record keeping and reporting requirements from each facility at this Source.
4. The requirement to keep the records of temperature at the inlet and outlet of the condensers to be replaced with a Quarterly Certification that the Condensers were operating at all times.
5. Condition regarding reporting malfunction, startup and shutdown to be incorporated in the Quarterly Certification above.
6. Modify reporting forms accordingly.

Subsequent to this request, the Permittee revisited the Reasonably Available Control Technology (RACT) determination for this source, which was prepared in 1993. The Permittee evaluated if there were any new development or advances in the control technology for this type of operation. It was determined that there was no change in the technical feasibility determination for different technologies. The economic feasibility of the controls have further decreased because the annual emissions would be reduced by half after this amendment (from 19.6 tons to 10 tons per year).

In the 1993 petition, both absorption/scrubbing and condensation were considered technically feasible options for Building 110. The cost-effectiveness of these two technologies was evaluated in detail in 1993 and found to be economically infeasible.

From the 1993 petition, the overall cost effectiveness for absorption/scrubbing to meet the Rule 8-5-3 requirements was \$47,110 per ton of VOC removed. Likewise, the overall cost-effectiveness of condensation to meet Rule 8-5-3 requirements was \$34,113 per ton of VOC removed.

Due to further reduction in the limit of VOC emission from this Source by half, the cost effectiveness for absorption/scrubbing to meet Rule 8-5-3 requirements would be \$94,220 per ton of VOC removed. The cost-effectiveness of condensation to meet Rule 8-5-3 requirements would be \$68,226 per ton of VOC removed. These costs are economically infeasible. Therefore, the RACT determination made in 1993 is still valid and there is no revision necessary to the RACT plan.

Recommendation

The staff recommends to the Commissioner that the Amendment to the Construction Permit be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on April 04, 2000. Additional information was received on February 14, 2001.

Conclusion

This permit amendment shall be subject to the conditions of the attached construction permit amendment letter 097-12128-00072.

Indiana Department of Environmental Management Office of Air Quality

Addendum to the Technical Support Document for an Amendment to a Construction Permit

Source Background and Description

Source Name:	Eli Lilly & Company – Lilly Technology Center
Source Location:	1555 South Harding Street, Indianapolis IN 46221
County:	Marion
SIC Code:	2834
Permit No.:	097-3341-00072
Operation Permit Issuance Date:	July 27, 1994
Amendment No.:	097-12128-00072
Permit Reviewer:	Gurinder Saini

On February 26, 2001, the Office of Air Quality (OAQ) had a notice published in the Indianapolis Star, Indianapolis, Indiana, stating that Eli Lilly & Company had applied for an amendment to their Construction Permit for Lilly Technology Center building B110 relating to the operation of research and development facilities.

The notice also stated that OAQ proposed to issue a permit amendment for this operation and provided information on how the public could review the proposed permit and other documentation. The notice informed interested parties that there was a period of thirty (30) days to provide comments on this permit as proposed. Finally, the notice informed the interested parties that a public hearing would be held related to this permit amendment on April 04, 2001 at 7:00 PM at the Marion County Central Library, 40 E. St. Clair, Cropsey Auditorium, Indianapolis, IN 46204.

The public hearing was organized at the above mentioned venue at the designated time and date by this office. No comments were received during this public hearing on this matter and no members of public participated in this public hearing.

During the comment period written comments were received from the Permittee related to this permit amendment. These comments and the OAQ response to these comments and any permit changes required are shown in the following paragraphs (**bolded** language has been added, the language with ~~strikeout~~ has been deleted):

Comment 1:

The Permittee has stated that a specific condition be added to the amendment letter to clarify that equipment operating in building B110, including equipment added after the effective date of the permit, is subject to the requirements of site-specific Reasonably Achievable Control Technology (RACT) plan as per 326 IAC 8-1-5 instead of 326 IAC 8-5-3 (b)(1) and (2) as determined in the construction permit.

The primary activity at the building B110 involves Research and Development (R and D) for manufacture of pharmaceutical products. Equipment which has the potential to emit greater than 15 pounds per day of VOC, and is used in the manufacture of pharmaceutical products is subject to the provisions 326 IAC 8-5-3.

As the new equipment is added to B 110 for R and D, the Permittee is required to either comply with provisions of 326 IAC 8-5-3 or submit a permit revision request. This permit revision request is to make the site specific RACT requirements in the Construction Permit 097-3341-00072 applicable to the newly added equipment.

The site-specific RACT requirements specified in CP 097-3341-00072 issued on July 27, 1997, allow the alternative control and monitoring requirements in lieu of 326 IAC 8-5-3 (b) (1) and (2) for equipment involved in manufacture of pharmaceutical products.

To reduce the number of revision requests and streamline the process of addition of R and D equipment, the Permittee is seeking that an advanced determination be made in this regard. The Permittee is requesting to add the language in the amendment letter which makes site-specific RACT requirements (in lieu of 326 IAC 8-5-3 (b) (1) and (2)) applicable to any new equipment added to the B 110 which has potential to emit VOC greater than 15 pounds per day and is used to manufacture pharmaceutical products.

Response 1:

On the page 2 of 6 of the amendment letter, the OAQ, IDEM has removed the equipment list from the construction permit and replaced it with Research and Development (R and D) activities as single process being carried out at the Building B110. The Permittee had requested to further lower the VOC emissions limit from this process to less than 10 tons per year from the original 19.01 tons per year in the construction permit. This revised emission level from this process and the designation as R and D are insignificant activities. Therefore, the new equipment added to Building B110 does not require any revision to the construction permit, if:

1. it is part of this R and D process;
2. complies with the site-specific RACT plan requirements specified in the construction permit; and
3. the source-wide emissions of VOC are still limited to less than 10 tons per year after the modification.

No change is made to the permit amendment letter.

Comment 2:

The Permittee has requested that a specific condition be added to the permit clarifying that the permitted equipment must comply with 326 IAC 8-5-3 (b) (3) through (6). The site-specific RACT plan provides alternate controls and monitoring methods for 326 IAC 8-5-2 (b) (1) and (2) only. The equipment which has potential to emit greater than 15 pounds per day of VOC still needs to comply with 326 IAC 8-5-3 (b) (3) through (6).

Response 2:

The OAQ, IDEM has decided to make this change. A new condition (d) is added to the amended condition 4 on the page 3 of 6 of the letter as follows:

- d) the emission units, which have potential to emit VOC greater than 15 pounds per day shall comply with requirements of 326 IAC 8-5-3 (b)(3) through (6) in addition to the site-specific RACT plan requirements.**

Comment 3:

The amended condition 4.a) on page 3 of 6 of the amendment letter limits the VOC emissions from the pilot plant in Building 110 to 0.834 tons per month. The Permittee has stated that this monthly limit is overly restrictive and inconsistent with the permitting practice. The Permittee has requested for a VOC emission limit of 10 tons per year, which should be rolled on a monthly basis.

Response 3:

The OAQ, IDEM has decided to make this change. The amended condition 4.a) on page 3 of 6 of the amendment letter is modified as follows:

- a) the volatile organic compound (VOC) emissions from pilot plant in Building 110 shall be limited to ~~0.834 tons per month~~ **less than 10 tons per 12 consecutive months period rolled on monthly basis;**

Comment 4:

The Permittee has stated that amended condition 4.c) on page 3 of 6 of the amendment letter implies that condensers are required to operate at all times. However condition 4.b) states when the condensers should be operated. Therefore, it should be stated in condition 4.c) that the condenser were operating as required by condition 4.b).

Response 4:

The OAQ, IDEM has made this change as follows:

- a) the applicant shall submit a quarterly certification that the condensers were operating **at all times as required by the condition 4.b**~~the time~~. If exceptions to this occur, note the exception, indicate what caused the exception, and how it was corrected.

Comment 5:

The amended condition 5 on page 3 of 6 of the amendment letter does not specify time-frame for submitting annual summary of VOC emissions. Permittee is requesting to add a time-frame of 60 days after the end of the calendar year to submit annual summary of VOC emissions.

Response 5:

The OAQ, IDEM has decided to make a change in the address for submitting reports in addition to the change mentioned in the above comment. The amended condition 5 is modified as follows:

5. A log of information necessary to document compliance with condition no.4, shall be maintained. These records shall be kept for at least the past 36 month period and made available upon request to the Office of Air Quality. The certification that the condensers were operating at all times shall be submitted quarterly to the following address:

Environmental Resources Management Division
Air Pollution Control Section
~~Enforcement Branch, Enforcement Manager~~
2700 South Belmont Avenue
Indianapolis, Indiana 46221

within 60 days after the end of the quarter. Additionally, an annual summary of volatile organic compounds (VOC) emissions shall also be submitted to above address. The VOC emissions shall be reported **within 60 days after the end of the calender year** in the format attached.

Comment 6:

The VOC reporting form on page 6 of 6 of the amendment letter needs to be modified to show limit of VOC emission based on 12 month rolling average.

Response 6:

The reporting form is modified as shown on the next page:

Indianapolis Air Pollution Control Section
Annual VOC Emissions Report

Eli Lilly and Company
Indianapolis, Indiana
Pollutant: VOC

Facility I.D.: B110 Pilot Plant
Construction Permit No.: CP 097-3341
Plt ID No.: 097-00072
Limit (tons per 12 month period **rolled on monthly basis**): 10 tons
~~Limit (tons per month): 0.834 tons~~

Monthly Emission Data

Year:

<u>Month</u>	<u>Tons VOC emitted this Month*</u>	<u>Tons VOC Emitted in Last 12 Months</u>
<u>December (previous year)</u>	<u></u>	<u></u>
<u>January</u>	<u></u>	<u></u>
<u>February</u>	<u></u>	<u></u>
<u>March</u>	<u></u>	<u></u>
<u>April</u>	<u></u>	<u></u>
<u>May</u>	<u></u>	<u></u>
<u>June</u>	<u></u>	<u></u>
<u>July</u>	<u></u>	<u></u>
<u>August</u>	<u></u>	<u></u>
<u>September</u>	<u></u>	<u></u>
<u>October</u>	<u></u>	<u></u>
<u>November</u>	<u></u>	<u></u>

* Production records that show compliance with this emission limit will be maintained on site and will be made available upon request.

Submitted By:
Date Submitted:

Comment 7:

The Permittee has requested to modify the VOC emission reporting form on page 6 of 6 of the amendment letter. This is to be modified to show months from January through December as per the proposed rule 326 IAC 2-6 for Marion County.

Response 7:

The change requested by Permittee is based on a proposed rule and can only be implemented when the rule is in force. Therefore, there is no change to the permit amendment.

Comment 8:

The Permittee has requested that the construction conditions 1 through 6 and operation conditions 1 through 3 of CP 097-3341-00072 should be deleted from the permit.

The Permittee has argued as follows:

“These conditions are obsolete, extraneous, or environmentally insignificant. The US EPA white paper on implementation of the Part 70 Operating Permit program suggests that NSR permit conditions which are obsolete, extraneous, environmentally insignificant or otherwise not required by the Clean Air Act, and which should not be incorporated into the Part 70 Operating Permit, are ripe for “purging” from the original preconstruction permit. (The conditions should be purged from the preconstruction permit because EPA considers preconstruction permits as having no expiration. This the terms apply until they are amended or deleted through an NSR modification.) If the terms are not purged, they must be incorporated into the Part 70 Operating Permit. Purging the obsolete, extraneous, or environmentally insignificant NSR terms as part of this amendment process will make the Part 70 Operating Permit issuance process easier.”

Further in this request Permittee has described in detail the reason why these conditions should be deleted from their permit as also described in their Part 70 Operating Permit Application.

Response 8:

The OAQ, IDEM does not agree with the company's recommendation for removing these conditions. The issue of removing conditions that are obsolete, extraneous, or environmentally insignificant will be handled during the Part 70 Operating Permit review process. The OAQ, IDEM has as a policy decided that it will not modify the permits to remove the construction conditions after the construction has been completed by the Permittee. No change is made to the permit amendment.

Comment 9:

The Permittee has requested that the first paragraph of the amendment letter should refer to March 30, 2000 as the date when the request for amendment was made.

Response 9:

The first paragraph of the amendment letter on page 1 of 6 is modified as follows:

Eli Lilly and Company was issued a permit on July 27, 1994 for research and development facilities. A letter requesting an amendment to the site specific RACT plan was received on ~~April~~ **March 30, 2000**.